

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

In re Application of:

Bertram CEZANNE et al.

Examiner: Noble E. Jarrel

Serial No.: 10/582,850

Group Art Unit: 1624

Filed: June 14, 2006

Title: CARBOXAMIDE DERIVATIVES

PETITION OF THE RESTRICTION REQUIREMENT UNDER 37 C.F.R. §1.181

TECHNOLOGY CENTER 1600

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is a petition requesting the Commissioner, through the Honorable Group Director, to reverse the Examiner's decision in instituting a Restriction within a single Markush claim and denying extension of the search beyond the elected invention. Specifically, applicants request that examination be performed on **the entire scope of presently pending claims 1-13 and 15.**

Statement of Facts

In the Office Action issued February 26, 2008, the Examiner presented a Restriction Requirement wherein applicants' compound genus was divided into 11 Groups, depending on the definitions of the variable groups Q, T and the combination of E, Z, and Z'. As noted in the Restriction, a Markush grouping (as presented in the claims in question) will satisfy PCT Rule 13.2 if the alternatives share a common property or activity and there is a significant common structural element shared by the alternatives. The Examiner asserted, however, that variable groups Z, Z', E, Q, and T provide "compounds that have achieved a different status in the art,

and thus are drawn to an improper Markush group.”

In the Amendment and Election filed March 28, 2008, applicants elected Group I, i.e., wherein Z, Z' and E form a piperidine ring, Q is absent, and T is a piperidine ring. However, applicants also traversed the Restriction Requirement. In the traversal, applicants pointed out that the Restriction acknowledged that a Markush grouping will satisfy PCT Rule 13.2 if the alternatives share a common property or activity and there is a significant common structural element shared by the alternatives. Thereafter, applicants argued that the compounds of the pending claims shared a common activity or property as discussed in applicants' specification. Additionally, applicants argued that the alternatives shared a common significant structure, namely a central piperidinyl ring, when Z, Z' and E form a piperidine ring. As a result, applicants requested that groups III, IV, and IX (as well as any relevant compounds within group XI) be examined with the elected Group I as to those compounds in which Z, Z' and E form a piperidine ring.

On October 29, 2008, the Examiner issued a Final Office Action. In this Office Action, the Examiner objected to claims 1-29 and 38-39 on grounds that the claims contained non-elected subject matter. The Examiner argued that “variable Q can only be a bond within the elected group and T can only be a piperidine ring that is optionally substituted.” The Examiner did not directly respond to applicants' arguments traversing the Restriction.

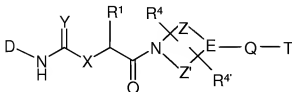
Summary of Argument in Support of Reversal of Denial to Extend the Search

Both the Examiner and applicants agree that a Markush grouping (as presented in the claims in question) will satisfy PCT Rule 13.2 if the alternatives share a common property or activity and there is a significant common structural element shared by the alternatives. Applicants have argued that the pending claims satisfy these requirements. Moreover, even where there is not a unifying common structure, the requirement of PCT Rule 13.2 that there be a technical interrelationship and the same or corresponding special technical feature will exist if the alternative of the Markush claim belongs to a recognized class of chemical compounds.

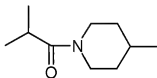
In making the Restriction, the Examiner argued that variable groups Z, Z', E, Q, and T provided compounds that have achieved a different status in the art. The Examiner therefore

concluded that the claims recited an improper Markush group. This assertion of achieving a different status in the art is a conclusion does not address whether the claims have a Markush group for unity of invention under PCR Rule 13.2. Moreover, this assertion is directed to the original claims, not the presently pending claims.

Applicants' independent claim 1 recites a genus of compounds defined by formula I:



As previously noted, the compounds of this genus shared a common significant structure, namely a central piperidinyl ring. In pending claim 1, groups Z, Z' and E are **not variable groups**, and these groups together with the N atom form a piperidine ring. Additionally, the common core structure additionally exhibits a carboxamide group. This common core structure is illustrated by the following subformula:



In addition to this significant common core structure, the compounds of the claimed genus share common properties. For example, the compounds exhibit factor Xa-inhibiting properties, and inhibitory activity with respect to coagulation factor VIIa, factor IXa, and thrombin in the blood coagulation cascade. See, e.g., page 4, lines 1-112 of applicants' specification.

The only comments made by the Examiner regarding the Restriction and the presently pending claims are found in the October 29, 2008 Final Office Action. As mentioned above, the Examiner argued that "variable Q can only be a bond within the elected group and T can only be a piperidine ring that is optionally substituted." This statement merely characterizes the elected subject matter. It does not present any rationale as to why the Restriction is being maintained.

In view of the above remarks, it is respectfully submitted that the members of the recited Markush group in applicants' claims share a significant common structure and share a common

property or activity. Thus, the pending claims satisfy the requirement of unity of invention under PCT Rules 13.1 and 13.2.

Furthermore, with respect to Markush claims, MPEP §803, entitled "Restriction - When Proper," states that "[i]nsofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP §803.02." The latter section of the MPEP states that: "[s]ince the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.**" (emphasis added)

Thereafter, the MPEP cites *In re Harnish*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d (Bd. Pat. App. & Int. 1984). These two cases both deal with improper Markush rejections. Thus, in the case of Markush claims, refusal by the Office to examine that which the applicants regard as their invention must be a refusal based on an improper Markush rejection.

Despite the explicit instructions set forth in the MPEP, the Examiner here is clearly seeking to make a Restriction within a claim. Applicants respectfully submit that 35 USC §121 does not permit restriction within a single claim as clearly indicated by the court in *In re Weber et al.*, 198 USPQ 328 (1978).

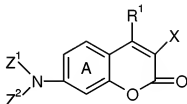
As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.

It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular claim on that same basis. [*Weber* at 331-332]

The effect of restriction within a single claim is the same as a rejection. 35 USC §121 does not

give the Commissioner authority to require that a single claim "be divided up and presented in several applications" and thus deny the Applicant the right to have that single claim considered on its merits. This is exactly the action that the Court in *Weber* stated was not permitted under 35 USC §121. Such action by an Examiner would violate "the basic right of the Applicant to claim his invention as he chooses." [*Weber* at 332]

Further, in the instant case, even if the Examiner had asserted that the subject matter of claim 1 lacked "unity of invention," and therefore should be restricted on grounds of an improper Markush rejection, it is clear that applicants' claims recite a proper Markush grouping. In this regard, the decision in *In re Harnisch*, 206 USPQ 300 (CCPA 1980) is relevant. In *Harnisch*, the claimed genus of compounds was defined by the following formula:



In this formula, Z¹ was defined as being H, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring. Z² was defined as being H, alkyl, cycloalkyl, or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring. In addition, Z¹ and Z² together with the nitrogen atom could represent an optionally benz-fused heterocyclic ring which "like ring A and the alkyl, aralkyl, cycloalkyl, and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry."

Thus, as can be seen, the definition of Z¹ and Z² encompassed a very wide variety of structures including various nitrogen containing heterocyclic structures such as morpholinyl, piperidyl, piperazinyl, etc. Yet, the Court in *Harnisch* reversed the improper Markush rejection noting that the claimed compounds were dyes and that the subgenus claimed was not repugnant to scientific classification.

As noted above, the compounds of applicants, claimed genus share a common property and exhibit a significant unchanging core structure. No rationale is presented in the Office Actions as to why applicants' claimed genus of compounds, with its significant core structure and

common activity, would be repugnant to scientific classification.

Conclusion

For the forgoing reasons, Applicants request reversal of the Examiner's decision to maintain the Restriction Requirement set forth in the February 26, 2008, and that examination be extended to the full scope of the pending claims.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: **MERCK-3185**

Date: December 29, 2008